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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/091,912

03/05/2002

Richard R. Bott

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ATTENTION: LEGAL DEPARTMENT  
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EXAMINER

STEADMAN, DAVID J

ART UNIT

PAPER NUMBER

1656

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/091,912	<b>Applicant(s)</b> BOTT ET AL.	
	<b>Examiner</b> David J. Steadman	<b>Art Unit</b> 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,39-41 and 45-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,39-41 and 45-55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of the Application***

**[1]** A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/7/09 has been entered.

**[2]** Claims 1, 39-41, and 45-55 are pending in the application.

**[3]** Applicant's remarks/arguments filed on 1/7/09 in response to the final Office action mailed on 7/8/08 have been fully considered. Rejections and/or objections not reiterated from previous Office actions are hereby withdrawn.

**[4]** The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

### ***Sequence Compliance***

**[5]** As noted in the prior Office action, in order to perfect sequence compliance, applicant should submit a specification amendment directing entry of the substitute sequence listing filed on 4/10/08 into the specification.

***Specification/Informalities***

**[6]** The objection to the specification under 35 U.S.C. 132(a) as introducing new matter into the disclosure is maintained for the reasons of record and the reasons set forth below. The objection was fully explained in a previous Office action. See particularly paragraph [9] of the Office action mailed on 7/8/08.

RESPONSE TO ARGUMENT: Applicant maintains the position that the specification provides adequate descriptive support for the amino acid sequence of SEQ ID NO:3. Beginning at p. 2 of the instant remarks, applicant supports this position by arguing "it would be apparent to one of skill...that the positions of mutations set forth in Tables 2 and 3 of the specification referred to the amino acid positions in the mature, processed sequence, without the leader sequence, because of the mismatch in the numbering between the tables and SEQ ID NO:2". According to applicant, SEQ ID NO:3 was added to the specification to correct an obvious defect, which is "evidenced by the amino acid numbering used in Tables 2 and 3" and "which differs from the numbering in SEQ ID NO:2 by 14 amino acids". Applicant argues the examiner has previously stated that the specification "shows possession of mutants of SEQ ID NO:2 *minus* a 14 amino acid leader sequence" (emphasis in original). Applicant further argues that SEQ ID NO:3 is "inherently contained in the original application within...SEQ ID NO:2 and in the numbering of...positions in Tables 2 and 3 and thus does not constitute new matter".

Applicant's argument is not found persuasive. Initially, it is noted that applicant's reliance on the examiner's previous statement is misplaced as the examiner's current

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position is clear – the specification fails to show support for SEQ ID NO:3. Applicant is kindly requested to show support for SEQ ID NO:3 in the original application, not by relying on the examiner's previous remarks.

The examiner maintains the position that the specification fails to provide adequate descriptive support for the amino acid sequence of SEQ ID NO:3. According to MPEP 2163.07.II, "An amendment to correct an obvious error does not constitute new matter where one skilled in the art would not only recognize the existence of error in the specification, but also the appropriate correction". It is acknowledged that the amino acid positions of Tables 2 and 3 do not correspond to the positions within SEQ ID NO:2 and thus one of skill in the art would recognize a discrepancy between the amino acid numbering of Tables 2 and 3 with respect to SEQ ID NO:2. However, one of skill in the art would NOT recognize the appropriate correction. Applicant asserts one of skill would have recognized that SEQ ID NO:3 – not SEQ ID NO:2 – was the intended sequence to be referenced throughout the claims and specification. However, the specification only refers to SEQ ID NO:2 and fails to mention or make reference to any modification of SEQ ID NO:2 to remove the N-terminal 14 amino acids. Indeed, the specification discloses, SEQ ID NO:2 "was subjected to the method of the invention" (p. 9, lines 10-11) and "Site-saturation variant libraries were created at amino acid positions corresponding to residue positions...of SEQ ID NO:2" (p. 10, lines 14-16). See also original claim 1. Based on the disclosure of the specification, it is the examiner's position that one of skill in the art would have instead recognized the appropriate correction to be an amendment to the specification to change the disclosed amino acid

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position numbering in Tables 1, 2, and 3 to correspond to the amino acid numbering of SEQ ID NO:2. As such, the sequence of SEQ ID NO:3 is not supported by the original description and thus constitutes new matter to the specification.

**[7]** The objection to the specification as failing to provide proper antecedent basis for the claimed subject matter is maintained for the reasons of record and the reasons set forth below. The objection was fully explained in a previous Office action. See particularly paragraph [10] of the Office action mailed on 7/8/08.

RESPONSE TO ARGUMENT: Applicant takes the position that the specification provides antecedent basis for the claimed subject matter. Beginning at p. 3 of the instant remarks, applicant supports this position by arguing SEQ ID NO:3 has been added to the specification by way of a sequence listing filed on 4/10/08.

Applicant's argument is not found persuasive. Although it is acknowledged that SEQ ID NO:3 has been added to the specification, there is no disclosure that provides antecedent basis in the specification for the limitations of the claims. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Appropriate correction is required.

### ***Claim Objection***

**[8]** Claims 1, 39, 45, and 53 are objected to in the recitation of "A variant of the *Pseudomonas mendocina* cutinase consisting of the amino acid sequence set forth in SEQ ID NO:3, wherein said variant consists of the amino acid sequence of SEQ ID NO:3, except..." In order to substantially improve claim form, it is suggested that the

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noted phrase be amended to recite, *e.g.*, "A variant of a *Pseudomonas mendocina* cutinase, wherein said variant consists of the amino acid sequence of SEQ ID NO:3, except..."

***Claim Rejections - 35 USC § 112, First Paragraph***

**[9]** The new matter rejection of claims 1, 39-41, and 45-55 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and the reasons set forth below. The rejection was fully explained in a previous Office action. See particularly paragraph [12] of the Office action mailed on 7/8/08.

RESPONSE TO ARGUMENT: Applicant maintains the position that the specification provides adequate descriptive support for the amino acid sequence of SEQ ID NO:3. At p. 4 of the instant remarks, applicant supports this position by arguing SEQ ID NO:3 is supported by SEQ ID NO:2 and the amino acid numbering Tables 2 and 3. Applicant further argues the examiner has previously stated that the specification "shows possession of mutants of SEQ ID NO:2 *minus* a 14 amino acid leader sequence" (emphasis in original).

Applicant's argument is not found persuasive. Initially, it is noted that applicant's reliance on the examiner's previous statement is misplaced as the examiner's current position is clear – the specification fails to provide adequate description of SEQ ID NO:3. Applicant is kindly requested to show support for SEQ ID NO:3 in the original application, not by relying on the examiner's previous remarks.

The examiner maintains the position that the specification fails to provide adequate descriptive support for the amino acid sequence of SEQ ID NO:3. According to MPEP 2163.07.II, "An amendment to correct an obvious error does not constitute new matter where one skilled in the art would not only recognize the existence of error in the specification, but also the appropriate correction". It is acknowledged that the amino acid positions of Tables 2 and 3 do not correspond to the positions within SEQ ID NO:2 and thus one of skill in the art would recognize the existence of error in the specification. However, one of skill in the art would NOT recognize the appropriate correction. Applicant asserts one of skill would have recognized that SEQ ID NO:3 – not SEQ ID NO:2 – was the intended sequence to be referenced throughout the claims. However, the specification only refers to SEQ ID NO:2 and fails to mention or make reference to any modification of SEQ ID NO:2 to remove the N-terminal 14 amino acids. Indeed, the specification discloses, SEQ ID NO:2 "was subjected to the method of the invention" (p. 9, lines 10-11) and "Site-saturation variant libraries were created at amino acid positions corresponding to residue positions...of SEQ ID NO:2" (p. 10, lines 14-16). See also original claim 1. Based on the disclosure of the specification, it is the examiner's position that one of skill in the art would have instead recognized the appropriate correction to be an amendment to the specification to change the disclosed amino acid positions in Tables 1, 2, and 3 to correspond to the amino acid numbering of SEQ ID NO:2. As such, the sequence of SEQ ID NO:3 is not supported by the original description and thus constitutes new matter to the specification.



***Claim Rejections - 35 USC § 103***

**[10]** The rejection of claim(s) 39-41 and 53-55 under 35 U.S.C. 103(a) as being unpatentable over Poulouse et al. (US Patent 5,352,594; reference A of the 1/29/04 PTO-892; hereafter referred to as “Poulouse”) is maintained for the reasons of record and the reasons set forth below. The rejection was fully explained in a previous Office action. See particularly paragraph [15] of the Office action mailed on 7/8/08.

**[11]** The rejection of claim(s) 45-52 under 35 U.S.C. 103(a) as being unpatentable over Poulouse is maintained for the reasons of record and the reasons set forth below. The rejection was fully explained in a previous Office action. See particularly paragraph [16] of the Office action mailed on 7/8/08.

**[12]** The rejection of claim(s) 1 under 35 U.S.C. 103(a) as being unpatentable over Poulouse in view of Schumann et al. (*Protein Sci* 2:1612-1620, 1993; reference U of the 11/14/07 PTO-892; hereafter referred to as “Schumann”), LoGrasso (*Biochemistry* 30:8463-8470, 1991; reference V of the 11/14/07 PTO-892; hereafter referred to as “LoGrasso”), and Cunningham et al. (*Prot Engineer* 1:319-325, 1987; reference W of the 11/14/07 PTO-892; hereafter referred to as “Cunningham”) is maintained for the reasons of record and the reasons set forth below. The rejection was fully explained in a previous Office action. See particularly paragraph [17] of the Office action mailed on 7/8/08.

RESPONSE TO ARGUMENT: Applicant maintains the position that the teachings of the reference of Poulouse alone or in combination fails to support a *prima facie* case of obviousness. Beginning at p. 4 of the instant remarks, applicant argues: 1) the Poulouse reference fails to teach any of the claimed variants; 2) the disclosure of Poulouse is merely an invitation to investigate; and 3) Poulouse does not teach screening for increased polyesterase activity and/or increased thermostability as recited in the claims.

Applicant's argument is not found persuasive. The examiner maintains the position that the claimed invention would have been obvious to one of ordinary skill in the art in view of the teachings of the reference of Poulouse alone or in combination with Schumann, LoGrasso, and Cunningham. As noted in prior Office actions, the examiner acknowledges that Poulouse fails to expressly disclose a variant having the recited mutations. However, this does not preclude a *prima facie* case of obviousness. Poulouse recognized a need to alter SEQ ID NO:3 to obtain variants with, *e.g.*, altered catalytic rate (*e.g.*, Abstract and columns 11-14). Poulouse undisputedly teaches a desire to mutate a polypeptide that is identical to SEQ ID NO:3 herein by altering "at least one amino acid...with a different amino acid, at a position within four (4) amino acid residues positions" of Ser126, His206, and Asp176 (see, *e.g.*, claims 4 and 6), pointing specifically to position 205 in, *e.g.*, claim 3. Also, Poulouse clearly recognizes the importance of mutations around position 176 as exemplified by, *e.g.*, claim 9. According to Poulouse the amino acids can be replaced by all 19 other possibilities (column 6, lines 45-47) and multiple mutants, including double and triple mutants, are

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envisioned (e.g., column 6, lines 47-49 and claim 3). As such, Poulouse clearly identifies a finite number of variants with predictable, potential solutions to achieve the mutants within 4 amino acids of positions 126, 176, and 206. Methods for producing such mutants are described by Poulouse (e.g., column 7) and such methods were undisputedly routine at the time of the invention. As noted above, Poulouse specifically points to a mutant at position 205. Also, Poulouse clearly recognizes the importance of mutations around position 176 as exemplified by, e.g., claim 9. Moreover, it is noted that Poulouse screens mutants by measuring changes in catalytic activity (e.g., columns 11-14). Even assuming *arguendo* Poulouse was not concerned with screening for mutants with increased catalytic activity, MPEP 2144.IV acknowledges that “The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant”. Also, although Poulouse does not appear to point out those particular variants within 4 amino acids of positions 126, 176, and 206 that will necessarily have the recited increased polyesterase activity or enhanced thermostability, since the function(s) of a polypeptide are a result of its structure, the recited function(s) would be a characteristic of the variants.

### ***Conclusion***

**[13]** Status of the claims:

- Claims 1, 39-41, and 45-55 are pending.

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- Claims 1, 39-41, and 45-55 are rejected.
- No claim is in condition for allowance.

All claims are drawn to the same invention and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in an earlier amendment. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Fri, 7:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David J. Steadman/  
Primary Examiner, Art Unit 1656